

FORM PTO-1449

APR 22 1999

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1053R2

Serial No.

08/948,149

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Fendly et al.

Filing Date

09 Oct 1997

Group

1641

U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	* 1	08/948,192		Fendly et al.			09.10.97
	* 2	09/119,152		Fendly et al.			20.07.98
	* 3	09/266,706		Fendly et al.			11.03.99
PMS	4	4,968,603	06.11.90	Slamon et al.	435	6	
AMS	5	5,183,884	02.02.93	Kraus et al.	536	23.5	
PME	6	5,480,968	02.01.96	Kraus et al.	530	326	
PME	7	5,641,869	24.06.97	Vandlen et al.	530	413	

FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes	No
PMS	8	599,274	01.06.94	EPO	C12N	15/12		
PMS	9	WO 89/06692	27.07.89	PCT	C12P	21/00		
MMS	10	WO 94/00136	06.01.94	PCT	A61K	35/14		
MMS	11	WO 94/22478	13.10.94	PCT	A61K	39/345		
PMS	12	WO 97/20858	12.06.97	PCT	C07K	16/32		

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

PMS	13	(Genentech, Inc. Proposal Request and Material Transfer Agreement with Richard H. Scheuermann (1993), 3 pages, and letters in relation to it dated June 23, 1993 and October 20, 1993)					
PMS	14	Aasland et al., "Expression of oncogenes in thyroid tumours: coexpression of c-erbB2/neu and c-erbB" <u>British Journal of Cancer</u> 57(4):358-363 (Apr 1988)					
PMS	15	Adams and Weiner, "Intracellular single-chain Fv antibodies--a knockout punch for neoplastic cells?" <u>Gynecologic Oncology</u> 59(1):6-7 (Oct 1995)					
PMS	16	Arboleda et al., "Effects of the 4D5 antibody on HER2/neu heterodimerization with other class I receptors in human breast cancer cells" <u>Proceedings of the American Association for Cancer Research</u> (Abstract #353) 37:51 (Mar 1996)					
PMS	17	Arteaga et al., "p185c-erbB-2 signaling enhances cisplatin-induced cytotoxicity in human breast carcinoma cells: association between an oncogenic receptor tyrosine kinase and drug-induced DNA repair" <u>Cancer Research</u> 54(14):3758-3765 (Jul 15, 1994)					
PMS	18	Bacus et al., "Differentiation of cultured human breast cancer cells (AU-565 and MCF-7) associated with loss of cell surface HER-2/neu antigen" <u>Molecular Carcinogenesis</u> 3(6):350-362 (1990)					
PMS	19	Bacus et al., "Tumor-inhibitory monoclonal antibodies to the HER-2/Neu receptor induce differentiation of human breast cancer cells" <u>Cancer Research</u> 52(9):2580-2589 (May 1, 1992)					
PMS	20	Baselga et al., "Receptor Blockade With Monoclonal Antibodies as Anti-Cancer Therapy" <u>Pharmac. Ther.</u> 64:127-154 (1994)					
PMS	21	Borst et al., "Oncogene alterations in endometrial carcinoma" <u>Gynecologic Oncology</u> 38(3):364-366 (Sep 1990)					
PMS	22	Carraway et al., "A Neu Acquaintance for ErbB3 and ErbB4: A Role for Receptor Heterodimerization in Growth Signaling" <u>Cell</u> 78:5-8 (July 15, 1994)					
PMS	23	Carter et al., "Humanization of an anti-p185HER2 antibody for human cancer therapy" <u>Proc. Natl. Acad. Sci.</u> 89:4285-4289 (1992)					

Examiner

R P Swartz

Date Considered

6-14-99

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

APR 22 1999

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1053R2

Serial No.

08/948,149

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Fendly et al.

Filing Date

09 Oct 1997

Group

1641

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

24	Cohen et al., "Expression pattern of the neu (NGL) gene-encoded growth factor receptor protein (p185neu) in normal and transformed epithelial tissues of the digestive tract" <u>Oncogene</u> 4(1):81-88 (Jan 1989)
25	D'souza et al., "Overexpression of ERBB2 in human mammary epithelial cells signals inhibition of transcription of the E-cadherin gene" <u>Proc. Natl. Acad. Sci. USA</u> 91(15):7202-7206 (Jul 19, 1994)
26	Darzynkiewicz et al., "Features of apoptotic cells measured by flow cytometry" <u>Cytometry</u> 13(8):795-808 (1992)
27	De Santes et al., "Radiolabeled Antibody Targeting of the HER-2/neu Oncoprotein" <u>Cancer Research</u> 52:1916-1923 (1992)
28	Deshane et al., "Intracellular antibody against erbB-2 mediates targeted tumor cell eradication by apoptosis" <u>Cancer Gene Therapy</u> 3(2):89-98 (Mar-Apr 1996)
29	Deshane et al., "Targeted eradication of ovarian cancer mediated by intracellular expression of anti-erbB-2 single-chain antibody" <u>Gynecologic Oncology</u> 59(1):8-14 (Oct 1995)
30	Deshane et al., "Targeted tumor killing via an intracellular antibody against erbB-2" <u>Journal of Clinical Investigation</u> 96(6):2980-2989 (Dec 1995)
31	Deshane et al., "Transductional Efficacy and Safety of an Intraperitoneally Delivered Adenovirus Encoding an Anti-erbB-2 Intracellular Single-Chain Antibody for Ovarian Cancer Gene Therapy" <u>Gynecologic Oncology</u> 64(3):378-385 (Mar 1997)
32	Digiesi et al., "Production and characterization of murine mAbs to the extracellular domain of human neu oncogene product GP185HER2" <u>Hybridoma</u> 11(4):519-527 (Aug 1992)
33	Drebin et al., "Down-Modulation of an Oncogene Protein Product and Reversion of the Transformed Phenotype by Monoclonal Antibodies" <u>Cell</u> 41(3):695-706 (1985)
34	Drebin et al., "Inhibition of tumor growth by a monoclonal antibody reactive with an oncogene-encoded tumor antigen" <u>Proc. Natl. Acad. Sci.</u> 83:9129-9133 (1986)
35	Drebin et al., "Monoclonal antibodies reactive with distinct domains of the neu oncogene-encoded p185 molecule exert synergistic anti-tumor effects in vivo" <u>Oncogene</u> 2:273-277 (1988)
36	Drebin et al., "Monoclonal Antibodies Specific for the neu Oncogene Product Directly Mediate Anti-tumor Effects In Vivo" <u>Oncogene</u> 2(4):387-394 (1988)
37	Fraker and Speck Jr., "Protein and cell membrane iodinations with a sparingly soluble chloroamide, 1,3,4,6-tetrachloro-3a,6a-diphenylglycoluril" <u>Biochemical & Biophysical Research Communications</u> 80(4):849-857 (Feb 28, 1978)
38	Fukushige et al., "Localization of a novel v-erbB-related gene, c-erbB-2, on human chromosome 17 and its amplification in a gastric cancer cell line" <u>Molecular & Cellular Biology</u> 6(3):955-958 (Mar 1986)
39	Grim et al., "The level of erbB2 expression predicts sensitivity to the cytotoxic effects of an intracellular anti-erbB2 sFv" <u>Journal of Molecular Medicine</u> 76(6):451-458 (May 1998)
40	Groenen et al., "Structure-function relationships for the EGF/TGF- α family of mitogens" <u>Growth Factors</u> 11:235-257 (1994)
41	Guerin et al., "Overexpression of either c-myc or c-erbB-2/neu proto-oncogenes in human breast carcinomas: correlation with poor prognosis" <u>Oncogene Research</u> 3(1):21-31 (1988)
42	Hancock et al., "A Monoclonal Antibody Against the c-erbB-2 Protein Enhances the Cytotoxicity of cis-Diamminedichloroplatinum Against Human Breast and Ovarian Tumor Cell Lines" <u>Cancer Research</u> 51:4575-4580 (September 1, 1991)
43	Harwerth et al., "Monoclonal antibodies against the extracellular domain of the erbB-2 receptor function as partial ligand agonists" <u>Journal of Biological Chemistry</u> 267(21):15160-15167 (Jul 1992)

Examiner

R P Swart

Date Considered

6-14-99

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1053R2

Serial No.

08/948,149

Applicant

Fendly et al.

Filing Date

09 Oct 1997

Group

1641

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

44	Hudziak et al., "Increased expression of the putative growth factor receptor p185 ^{HER2} causes transformation and tumorigenesis of NIH 3T3 cells" <u>Proc. Natl. Acad. Sci.</u> 84:7159-7163 (1987)
45	Hudziak et al., "p185 ^{HER2} Monoclonal Antibody Has Antiproliferative Effects In Vitro and Sensitizes Human Breast Tumor Cells to Tumor Necrosis Factor" <u>Molecular & Cellular Biology</u> 9(3):1165-1172 (1989)
46	Ilgen et al., "Characterization of anti-HER/2 antibodies which inhibit the growth of breast tumor cells in vitro" <u>Proceedings of the American Association for Cancer Research</u> (abstract #3209) 37:470 (Mar 1996)
47	Ilgen et al., "Characterization of anti-HER/2 monoclonal antibodies which inhibit the growth of breast cancer cell lines in vitro" <u>Proceedings of the American Association for Cancer Research</u> (Abstract #564) 38:84 (Mar 1997)
48	Kasprzyk et al., "Therapy of an animal model of human gastric cancer using a combination of anti-erbB-2 monoclonal antibodies" <u>Cancer Research</u> 52(10):2771-2776 (May 15, 1992)
49	Kern et al., "p185 ^{neu} expression in human lung adenocarcinomas predicts shortened survival" <u>Cancer Research</u> 50(16):5184-5191 (Aug 15, 1990)
50	King et al., "Amplification of a Novel v-erbB-Related Gene in a Human Mammary Carcinoma" <u>Science</u> 229:974-976 (1985)
51	Kotts et al., "Differential growth inhibition of human carcinoma cells exposed to monoclonal antibodies directed against the extracellular domain of the HER2/ERBB2 protooncogene" <u>In Vitro</u> (Abstract #176) 26(3):59A (1990)
52	Kotts et al., "Differential Growth Inhibition of Human Carcinoma Cells Exposed to Monoclonal Antibodies Directed Against the Extracellular Domain of the HER2/ERBB2 Protooncogene" (poster presented at the Annual Meeting of the Tissue Culture Association held in Houston, Texas on June 1990) pps. 1-13
53	Kumar et al., "Regulation of phosphorylation of the c-erbB-2/HER2 gene product by a monoclonal antibody and serum growth factor(s) in human mammary carcinoma cells" <u>Molecular & Cellular Biology</u> 11(2):979-986 (Feb 1991)
54	Lee et al., "Transforming growth factor α : expression, regulation, and biological activities" <u>Pharmacological Reviews</u> 47(1):51-85 (Mar 1995)
55	Lemke, "Neuregulins in Development" <u>Molecular and Cellular Neuroscience</u> 7:247-262 (1996)
56	Levi et al., "The influence of Heregulins on Human Schwann Cell Proliferation" <u>J. Neuroscience</u> 15(2):1329-1340 (February 1995)
57	Lewis et al., "Growth regulation of human breast and ovarian tumor cells by heregulin: Evidence for the requirement of ErbB2 as a critical component in mediating heregulin responsiveness" <u>Cancer Research</u> 56:1457-1465 (1996)
58	Maier et al., "Requirements for the internalization of a murine monoclonal antibody directed against the HER-2/neu gene product c-erbB-2" <u>Cancer Research</u> 51(19):5361-5369 (Oct 1, 1991)
59	Marth et al., "Effects of interferons on the expression of the proto-oncogene HER-2 in human ovarian carcinoma cells" <u>International Journal of Cancer</u> 50(1):64-68 (Jan 2, 1992)
60	Masui et al., "Growth inhibition of human tumor cells in athymic mice by anti-epidermal growth factor receptor monoclonal antibodies" <u>Cancer Research</u> 44(3):1002-1007 (Mar 1984)
61	McCann et al., "c-erbB-2 oncoprotein expression in primary human tumors" <u>Cancer</u> 65(1):88-92 (Jan 1, 1990)
62	McKenzie et al., "Generation and characterization of monoclonal antibodies specific for the human neu oncogene product, p185" <u>Oncogene</u> 4:543-548 (1989)
63	Moore et al., "Apoptosis in CHO Cell Batch Cultures: Examination by Flow Cytometry" <u>Cytotechnology</u> 17:1-11 (1995)

Examiner

BPSwamy

Date Considered

6-14-99

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1053R2

Serial No.

08/948,149

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Fendly et al.

Filing Date

09 Oct 1997

Group

1641

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

64	Morrissey et al., "Axon-induced mitogenesis of human Schwann cells involves heregulin and p185 ^{erbB2} " <u>Proc. Natl. Acad. Sci. USA</u> 92:1431-1435 (Feb 1995)
65	Myers et al., "Biological Effects of Monoclonal Antireceptor Antibodies Reactive with neu Oncogene Product, p185 ^{neu} " <u>Methods in Enzymology</u> 198:277-290 (1991)
66	Park et al., "Amplification, overexpression, and rearrangement of the erbB-2 protooncogene in primary human stomach carcinomas" <u>Cancer Research</u> 49(23):6605-6609 (Dec 1, 1989)
67	Pickler et al., "Control of lymphocyte recirculation in man. I. Differential regulation of the peripheral lymph node homing receptor L-selectin on T cells during the virgin to memory cell transition" <u>Journal of Immunology</u> 150(3):1105-1121 (Feb 1, 1993)
68	Pietras et al., "Antibody to HER-2/neu Receptor Blocks DNA Repair After Cisplatin in Human Breast and Ovarian Cancer Cells" <u>Oncogene</u> 9:1829-1838 (1994)
69	Plowman et al., "Heregulin induces tyrosine phosphorylation of HER4/p180 ^{erbB4} " <u>Nature</u> (Letters to Nature) 366:473-475 (Dec 2, 1993)
70	Plowman et al., "Ligand-specific activation of HER4/p180 ^{erbB4} , a fourth member of the epidermal growth factor receptor family" <u>Proc. Natl. Acad. Sci. USA</u> 90:1746-1750 (1993)
71	Price et al., "Tumorigenicity and metastasis of human breast carcinoma cell lines in nude mice" <u>Cancer Research</u> 50(3):717-721 (Feb 1, 1990)
72	Sarup, "Characterization of an Anti-P185 ^{HER2} Monoclonal Antibody that Stimulates Receptor Function and Inhibits Tumor Cell Growth" <u>Growth Regulation</u> 1:72-82 (1991)
73	Scheuermann, R., "Anti-HER2 Effects" (slide which may have been (but was probably not) presented at a seminar by Scheuermann at Syntex on August 3, 1994)
74	Schlom, J., "Monoclonal Antibodies: They're More and Less Than You Think" <u>Molecular Foundations of Oncology</u> , Broder, S. ed., Baltimore, MD:Williams & Wilkins, Chapter 6, pps. 95-134 (1991)
75	Scott et al., "p185 ^{HER2} signal transduction in breast cancer cells" <u>Journal of Biological Chemistry</u> 266(22):14300-14305 (Aug 5, 1991)
76	Shawver et al., "Ligand-like effects induced by anti-c-erbB-2 antibodies do not correlate with and are not required for growth inhibition of human carcinoma cells" <u>Cancer Research</u> 54(5):1367-1373 (Mar 1, 1994)
77	Slamon et al., "Human Breast Cancer: Correlation of Relapse and Survival with Amplification of the HER-2/neu Oncogene" <u>Science</u> 235:177-182 (1987)
78	Slamon, et al., "Studies of the HER-2/neu Proto-oncogene in Human Breast and Ovarian Cancer" <u>Science</u> 244:707-712 (May 1989)
79	Sliwkowski et al., "Coexpression of erbB2 and erbB3 proteins reconstitutes a high affinity receptor for heregulin" <u>Journal of Biological Chemistry</u> 269(20):14661-14665 (1994)
80	Sliwkowski et al., "A humanized monoclonal antibody for the treatment of HER2 overexpressing breast cancer" <u>Proceedings of the American Association for Cancer Research</u> 37:625-626 (Mar 1996)
81	Stancovski et al., "Mechanistic aspects of the opposing effects of monoclonal antibodies to the ERBB2 receptor on tumor growth" <u>Proc. Natl. Acad. Sci. USA</u> 88(19):8691-8695 (Oct 1, 1991)
82	Tagliabue et al., "Selection of monoclonal antibodies which induce internalization and phosphorylation of p185 ^{HER2} and growth inhibition of cells with HER2/NEU gene amplification" <u>International Journal of Cancer</u> 47(6):933-937 (Apr 1, 1991)
83	Trauth et al., "Monoclonal antibody-mediated tumor regression by induction of apoptosis" <u>Science</u> 245:301-305 (1989)

Examiner

R P Swartz

Date Considered

6-14-99

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1053R2

Serial No.

08/948,149

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Fendly et al.

Filing Date

09 Oct 1997

Group

1641

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

84	Vitetta et al., "Monoclonal antibodies as agonists: an expanded role for their use in cancer therapy" <u>Cancer Research</u> 54(20):5301-5309 (Oct 15, 1994)
85	Vollmers et al., "Apoptosis of stomach carcinoma cells induced by a human monoclonal antibody" <u>Cancer</u> 76(4):550-558 (Aug 15, 1995)
86	Weiner et al., "Expression of the neu gene-encoded protein (P185 ^{neu}) in human non-small cell carcinomas of the lung" <u>Cancer Research</u> 50(2):421-425 (Jan 15, 1990)
87	Weller et al., "Anti-Fas/APO-1 antibody-mediated apoptosis of cultured human glioma cells. Induction and modulation of sensitivity by cytokines" <u>Journal of Clinical Investigation</u> 94(3):954-964 (Sep 1994)
88	Williams et al., "Expression of c-erbB-2 in human pancreatic adenocarcinomas" <u>Pathobiology</u> 59(1):46-52 (1991)
89	Wright et al., "An intracellular anti-erbB-2 single-chain antibody is specifically cytotoxic to human breast carcinoma cells overexpressing erbB-2" <u>Gene Therapy</u> 4(4):317-322 (Apr 1997)
90	Wu et al., "Apoptosis induced by an anti-epidermal growth factor receptor monoclonal antibody in a human colorectal carcinoma cell line and its delay by insulin" <u>Journal of Clinical Investigation</u> 95(4):1897-1905 (Apr 1995)
91	Xu et al., "Antibody-induced growth inhibition is mediated through immunochemically and functionally distinct epitopes on the extracellular domain of the c-erbB-2 (HER-2/neu) gene product p185" <u>International Journal of Cancer</u> 53(3):401-408 (Feb 1, 1993)
92	Yamamoto et al., "Similarity of protein encoded by the human c-erbB-2 gene to epidermal growth factor receptor" <u>Nature</u> 319:230-234 (1986)
93	Yokota et al., "Amplification of c-erbB-2 oncogene in human adenocarcinomas in vivo" <u>Lancet</u> 1(8484):765-767 (Apr 5, 1986)
94	Yonemura et al., "Evaluation of immunoreactivity for erbB-2 protein as a marker of poor short term prognosis in gastric cancer" <u>Cancer Research</u> 51(3):1034-1038 (Feb 1, 1991)
95	Zhang et al., "Relative malignant potential of human breast carcinoma cell lines established from pleural effusions and a brain metastasis" <u>Invasion Metastasis</u> 11(4):204-215 (1991)
96	Zhou et al., "Amplification and expression of the c-erb B-2/neu proto-oncogene in human bladder cancer" <u>Molecular Carcinogenesis</u> 3(5):254-257 (1990)

Examiner

R P Swart

Date Considered

6-14-99

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.